

DEPARTMENT OF THE ARMY  
HEADQUARTERS, WALTER REED ARMY MEDICAL CENTER  
6900 Georgia Avenue, NW  
Washington, DC 20307-5001

WRAMC Regulation  
No. 40-96

28 June 2002

Medical Services  
**INFORMED CONSENT**

**1. History**

This policy is a revision of the previous policy. The changes have not been highlighted.

**2. Applicability**

Applies to all Walter Reed Army Medical Center (WRAMC) Health Care Providers.

**3. Purpose**

To provide information on what constitutes informed consent and how it is obtained.

**4. References**

- a. AR 40-400, *Patient Administration*, 12 March 2001.
- b. WRAMC Reg 40-24, *Transfusion of Blood and Blood Products*, 26 March 2002.
- c. *Canterbury v. Spence and the Washington Hospital Center*, 464 F.2d 772 (DC Cir., 1972).
- d. D.C. Code § 21-2202 (Definitions).
- e. D.C. Code § 21-2204 (Certification of Incapacity).
- f. D.C. Code § 21-2210 (Substituted consent).

**5. Explanation of Abbreviations and Terms**

a. Informed Consent – Consent obtained from a patient after disclosure in non-technical terms of the nature of the proposed treatment or therapy and broadly accepted alternatives; goals expected or believed to be achieved; the most likely expected complications of the proposed treatment and alternatives discussed; and risks which may ensue from the proposed treatment and the discussed alternative therapies. Patient education must always include broadly accepted alternatives in the medical community, including no treatment. A written consent form serves as a memorandum of the understanding between the patient and his/her physician or other health care provider. A detailed counseling note by the provider documenting the specific information provided the patient is essential to complete the informed consent process.

b. Express (Informed) Consent - A written or oral statement by a patient or a person with the legal authority to act on a patient's behalf. Consent is given to proposed medical care after full disclosure and due consideration of the following:

- (1) The nature and character of the proposed treatment and/or procedure to be performed.
- (2) The anticipated results of the proposed treatment and/or procedure.

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\*This regulation supersedes WRAMC Regulation 40-96, 10 Jun 99.

(3) The recognized broadly accepted alternative forms of treatment, including no treatment.

(4) The recognized serious risks, possible complication and anticipated benefits in the proposed treatment and alternative forms of treatment, including no treatment.

c. Implied Consent – When there is an emergency (*i.e.*, Immediate treatment is necessary to preserve life or prevent serious deterioration of a patient's condition.), and the patient is unable to make an informed decision and the consent of a person qualified to represent him/her is not reasonably available, consent to treatment is implied by law and express consent is not required. The implied consent in an emergency is to the treatment of the condition giving rise to the emergency only. The medical record must clearly define the nature of the emergency and specify the threat to life or health and clearly document all attempts to obtain express consent from the substitute or surrogate decision-maker.

d. Incompetency / Incapacity – Under District of Columbia law, for the purposes of giving informed consent for health care, an incompetent is a person who is under the age of 18, or is incapable of understanding the health-care choice, making a decision concerning the particular treatment or services in question, or communicating a decision even if capable of making it. (D.C. Code § 21-2202(5): "Incapacitated individual means an adult individual who lacks sufficient mental capacity to appreciate the nature and implications of a health-care decision, make a choice regarding the alternative presented or communicate that choice in an unambiguous manner").

e. Substitute or Surrogate decision-maker – A person authorized under applicable local law, court order or power of attorney to consent to medical care on behalf of an incompetent or incapacitated patient.

f. Written consent must be obtained before performing the procedures outlined in paragraph 7. b. or 7.c. of this regulation.

## **6. Responsibilities**

a. The Physician, Dentist, or Credentialed Licensed Independent Provider will counsel the patient or his/her substitute decision-maker regarding the nature and extent of the proposed procedure or treatment and broadly accepted alternatives, including no treatment, ensuring that there is a clear understanding of the expected outcomes, benefits, risks, and most likely expected complications of the proposed treatment and the alternatives. This counseling must be attested by signatures of the counseling health care provider and the consenting patient or his (her) substitute decision-maker on the WRAMC OP 24 (Request for Administration of Anesthesia and for Performance of Operations and Other Procedures).

b. The Officer in Charge and/or Head Nurse of each ward/clinic will ensure that all personnel in that unit have been informed of the contents of this policy and know where to locate it if needed.

c. The Directors of Departments/Chiefs of Services will ensure that all Credentialed Licensed Independent Providers under their supervision are familiar with this policy and its requirements.

d. Nursing personnel are responsible for ensuring that:

(1) The Medical Record Request for Administration of Anesthesia and for Performance of Operations and Other Procedures (WRAMC OP 24), is completely filled out and signed prior to administering any pre-medications.

(2) If personal or telephonic counseling has taken place with a substitute or surrogate decision-maker, that it is clearly documented on the Doctor's Progress Notes.

(3) The physician is notified immediately if:

(a) The consent form, OF 522-WRAMC OP 24, is not completely filled out and signed before the procedure.

(b) The patient still has any unanswered questions.

(c) The patient refuses to sign the consent for any reason.

e. Questions regarding the legal sufficiency of informed consent should be addressed to the Office of the Center Judge Advocate at 782-1550. After duty hours, an attorney can be contacted through the Administrative Officer of the Day at 782-7309.

## **7. Policies**

a. It is the responsibility of all Credentialed Licensed Independent Providers to obtain informed consent under the circumstances described below. Informed consent is obtained when the health care provider counsels the patient or his/her substitute decision-maker of the nature and extent of the proposed procedure or treatment and broadly accepted alternative therapies, including no treatment, with a clear understanding of the expected outcomes, risks, benefits, and most likely possible complications and the patient decides to proceed.

b. As required by AR 40-400, *Patient Administration*, or WRAMC command policy, the following general categories of treatment require written consent (WRAMC OP 24):

(1) All surgery involving entry into the body by an incision or through one of the natural body openings.

(2) Any procedure or course of treatment in which anesthesia or sedation is used, whether or not entry into the body is involved. This includes dental procedures involving the use of general anesthetic, intravenous sedation, or nitrous oxide sedation.

(3) All nonoperative procedures that involve more than a slight risk of harm to the patient or that involve the risk of a change in body structure.

(4) All procedures in which radiation, or other radioactive substances are used in the patient's treatment.

(5) All procedures that involve electroshock or electroconvulsive therapy.

(6) All transfusions of blood or blood products.

(a) Single completed informed consent documentation is sufficient for one or more transfusions of blood and blood products for each hospitalization.

(b) For chemotherapy patients and other chronically ill patients, single informed consent documentation in the outpatient medical record is sufficient for the entire course of outpatient therapy.

(7) All procedures involving needle or catheter aspiration, drainage or biopsy. This does not include placement and aspiration of peripheral intravenous catheters or needles. Placement of a central intravenous catheter via peripheral insertion site (peripherally inserted central catheter [PICC]) does require a signed written consent.

(8) All procedures requiring the injection of intravenous contrast material.

(9) All other procedures that, in the opinion of the attending physician, dentist, chief of service, clinic chief, or the commander, require a written consent. Any question about the necessity or advisability of a written consent should be resolved in favor of obtaining such an informed consent.

c. All research protocols, utilizing investigational agents or procedures, require that consent for the research treatment or procedure be obtained from the participant on a consent form approved by the WRAMC Human Use Committee (Institutional Review Board), in addition to any other consent required by a procedure or treatment in one of the categories in paragraph 7.b., above.

d. When a written consent is required, every effort should be made to secure the signature of the patient or a substitute decision-maker. Consent will be implied in emergency situations when patients are incapable of either giving consent or declining treatment and their condition represents a serious and imminent threat to life, health or well-being. After the exhaustion of all efforts to locate a substitute decision-maker when an emergency does not exist and the patient is incompetent or lacks capacity to consent, contact the Office of the Center Judge Advocate at 782-5810/1550. After duty hours, an attorney can be contacted through the Administrative Officer of the Day, 782-7309.

e. Substitute or Surrogate Consent:

(1) All adult (18 years old or older) patients are presumed to be competent to make health-care decisions, unless or until another person is given the power to make health-care decisions for an incompetent or incapacitated adult patient, either through judicial action or by the patient when still competent.

(2) In instances where there has been a determination made by a court that an individual is not competent, a court-appointed guardian will be the substitute or surrogate decision maker. The court-appointed guardian's decisions will take precedence over the desires of the patient or a surrogate appointed by a health-care power of attorney.

(3) When it appears that a patient is incompetent, and there is neither a court-appointed guardian nor a valid health-care power of attorney, an individual will be designated to grant, withdraw, or decline consent on behalf of the patient pursuant to the laws of the District of Columbia. After the incapacity of the patient has been certified under D.C. Code § 21-2204, an individual available from the highest of the following classifications of priority is appointed to make decisions involving consent:

(a) The spouse of the patient.

(b) An adult child of the patient.

(c) A parent of the patient.

(d) An adult sibling of the patient.

(e) A religious superior of the patient, if the patient is a member of a religious order or a diocesan priest.

(f) The nearest living relative of the patient.

f. Certification of Incapacity pursuant to D.C. Code § 21-2204:

(1) Mental incapacity to make a health care decision shall be certified by two (2) licensed physicians qualified to make a determination of mental incapacity. One of the certifying physicians must be a psychiatrist. At least one of the two physicians must examine the individual in question within one day preceding the certification of incapacity. Both certifying physicians must give an opinion

regarding the cause and nature of the mental incapacity as well as its extent and probable duration.

(2) All examination findings and opinions forming the basis of the certification must be written and included in the medical records of the patient, and provide clear evidence that the person is incapable of understanding the health-care choices, making a decision concerning the particular treatment or services in question, or communicating a decision, even if capable of making it.

g. Consent by a Minor:

(1) A minor is a person under 18 years of age.

(2) Though a minor's consent is not legally sufficient, the minor's assent should still be sought whenever the minor is able to understand the significance of the proposed procedure.

(3) Consent for non-emergent treatment must be obtained from a parent, court-appointed guardian, or the holder of a valid health care power-of-attorney.

(4) Exceptions:

(a) Health care may be provided to a minor of any age without parental consent, when in the judgment of the treating physician, surgeon or dentist, the delay that would result from attempting to obtain parental consent would substantially increase the risk to the minor's life, physical health, mental health or welfare, or would unduly prolong suffering.

(b) Minors who are members of the uniformed services are emancipated and can give consent as if they were adults. An emancipated minor may also give consent for medical care for his/her minor child/children.

(c) A minor of any age may consent to health care which he or she requests for the prevention, diagnosis or treatment of (1) pregnancy, (2) substance abuse, and (3) mental or emotional conditions and sexually transmitted diseases. Minors may not consent to sterilization.

h. The original written consent remains valid when a procedure is delayed, providing that:

(1) The procedure that was the subject of the original consent is still planned, and

(2) There has been no break in the patient's period of hospitalization, and

(3) The patient's condition has not changed materially from the time the consent was obtained.

## APPENDIX A

## WALTER REED INFORMED CONSENT

522-113

NSN 7540-00-634-4165

## MEDICAL RECORD

REQUEST FOR ADMINISTRATION OF ANESTHESIA  
AND FOR PERFORMANCE OF OPERATIONS AND OTHER PROCEDURES

## A. IDENTIFICATION

1. OPERATION OR PROCEDURE ☐ ANESTHESIA ☐ SEDATION ☐ TRANSFUSION (see back of form) ☐Check All  
Indicated Boxes

## B. STATEMENT OF REQUEST

1. The nature and purpose of the operation or procedure, possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me. I acknowledge that no guarantees have been made to me concerning the results of the operation or procedure. I understand the nature of the operation or procedure to be \_\_\_\_\_

(Description of operation or procedure in layman's language)

which is to be performed by or under the direction of Dr. \_\_\_\_\_

2. I request the performance of the above-named operation or procedure and of such additional operations or procedures as are found to be necessary or desirable, in the judgment of the professional staff of the below-named medical facility, during the course of the above-named operation or procedure.

3. I request the administration of such anesthesia as may be considered necessary or advisable in the judgment of the professional staff of the below-named medical facility.

4. Exceptions to surgery or anesthesia, if any, are: \_\_\_\_\_

(If "none", so state)

5. I request the disposal by authorities of the below-named medical facility of any tissues or parts which it may be necessary to remove.

6. I understand that photographs and movies may be taken of this operation, and that they may be viewed by various personnel undergoing training or indoctrination at this or other facilities. I consent to the taking of such pictures and observation of the operation by authorized personnel, subject to the following conditions:

- a. The name of the patient and his/her family is not used to identify said pictures.
- b. Said pictures be used only for purposes of medical/dental study or research.

(Cross out any parts above which are not appropriate)

## C. SIGNATURES (Appropriate items in Parts A and B must be completed before signing)

1. COUNSELING PHYSICIAN/DENTIST: I have counseled this patient as to the nature of the proposed procedure(s), attendant risks involved, and expected results, as described above. I have also discussed potential problems related to Anesthesia/Sedation/Transfusion, as noted above, and to recuperation, possible results of non-treatment, and significant alternative therapies.

(Signature of Counseling Physician/Dentist)  
Licensed Independent Provider

2. PATIENT: I understand the nature of the proposed procedure(s), attendant risks involved, and expected results, as described above, and hereby request such procedure(s) be performed. I am aware of potential problems related to Anesthesia/Sedation/Transfusion, as noted above, and to recuperation, possible results of non-treatment, and significant alternative therapies.

(Signature of Witness, excluding members of operating team)

(Signature of Patient)

(Date and Time)

3. SPONSOR OR GUARDIAN: (When patient is a minor or unable to give consent) I, \_\_\_\_\_ sponsor/guardian of \_\_\_\_\_ understand the nature of the proposed procedure(s), attendant risks involved, and expected results, as described above, and hereby request such procedure(s) be performed. I am aware of potential problems related to Anesthesia/Sedation/Transfusion, as noted above, and to recuperation, possible results of non-treatment, and significant alternative therapies.

(Signature of Witness, excluding members of operating team)

(Signature of Sponsor/Legal Guardian)

(Date and Time)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle; grade; rank; rate; hospital or medical facility)

REGISTER NO.

WARD NO.

REQUEST FOR ADMINISTRATION OF ANESTHESIA AND FOR  
PERFORMANCE OF OPERATIONS AND OTHER PROCEDURES

Medical Record

★ U.S. GOVERNMENT PRINTING OFFICE: 1985-390-867

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APPENDIX A (Continued)  
OF 522-WRAMC OP24

July 2002

During the course of your treatment at Walter Reed Army Medical Center, you may receive a transfusion of one or more blood products. Your physician will outline the expected benefits of such a procedure to you. WRAMC (and the entire military blood banking community) complies with all of the stringent regulatory standards designed to make our blood as safe as possible. Despite this, there are several well-established risks of transfusion. These risks are outlined below.

### 1. Transmission of Infectious Diseases

Each potential blood donor is screened very carefully before donation to ensure maximum safety of the blood that he is donating, and each unit of blood is tested for infectious agents prior to transfusion. We constantly strive to improve our ability to detect infectious agents. However, transmission of infectious agents is still a possibility. The table below outlines the currently accepted estimates of risk of infectious agent transmission per unit transfused.

Hepatitis B virus	Less than 1 in 100,000 units transfused
Hepatitis C virus	Less than 1 in 1 million units transfused
HTLV (a white cell virus)	1 in 641,000 units transfused
HIV virus (AIDS virus)	Less than 1 in 1 million units transfused

### 2. Fever

Mild increases in temperature, accompanied by chills, are not uncommon following transfusion. Your physician may give you Tylenol before your transfusion to prevent this. It is very important that you report any chills you have during your transfusion to your nurse or physician, because in very rare instances, fever may indicate a more significant problem.

### 3. Allergic reactions

Occasionally, your body may respond to transfusion with an allergic reaction. These reactions are generally very mild, and include itching and rash. Your physician may give you Benadryl before your transfusion to prevent this. Very rarely, more serious allergic reactions may occur and cause breathing problems, throat swelling, or low blood pressure. Again, please report any problems you have during your transfusion, no matter how small they may seem, to your nurse or physician.

### 4. Hemolysis

Very rarely, the blood that is transfused to you can be destroyed by your body, leading to potentially harmful effects. Your physician, the nursing staff, and the WRAMC Blood Bank go to great lengths to ensure that this doesn't occur. For your part, you may again help by reporting anything unusual you feel during your transfusion to your nurse and/or physician.

### 5. Complications of Massive Transfusion

If you require a very large amount of blood in a very short time frame, metabolic problems such as electrolyte imbalance or body temperature changes may occur. In addition, your normal clotting factors may be diluted. Your physician can give you more information regarding the management of these potential problems.

The above should introduce the major risks of transfusion. You should be aware that for some patients, there are alternatives to transfusion of banked blood. These alternatives include such things as preoperative donation of your own blood for use during or after surgery, intraoperative salvage of your blood, and administration of certain drugs to boost your own level of blood cells. Your physician can supply you with additional details about some of these alternatives.

The Blood Bank is always available to help answer any other questions that you may have about blood transfusion. Feel free to call us at (202) 782-6989 for additional information.

WRAMC Reg 40-96

**The proponent agency of this publication is the office of the Directorate of Patient Administration. Send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, Walter Reed Army Medical Center, ATTN: MCHL-PAD, 6900 Georgia Avenue, NW, Washington, DC 20307-5001.**

FOR THE COMMANDER:

OFFICIAL:

JAMES R. GREENWOOD  
COL, MS  
Deputy Commander for  
Administration

A handwritten signature in black ink, appearing to read 'ERIK J. GLOVER', is written over the printed name and title.

ERIK J. GLOVER  
MAJ, MS  
Executive Office

DISTRIBUTION:

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